

REMARKS

Claim Amendments

Claims 190, 199, 208, 217 and 249-255 have been amended to delete the language “the same or” such that the limitation in the amended claims with respect to the amplification of the reference RNA sequence and the target viral RNA sequence now reads “can be amplified by different oligonucleotides.”

Applicants submit that this amendment does not constitute new matter and its entry is requested.

Summary of the Claimed Invention

A. Amplification of Target Viral RNA Sequence and Reference RNA Sequence

In a first aspect, claims 190-225 and 242-245 are directed to a method for the amplification of target viral RNA and a reference RNA in a sample. In accordance with this aspect, (i) a known quantity of a reference RNA sequence is added to a sample containing a viral RNA sequence, (ii) the target viral RNA sequence and the reference RNA sequence are simultaneously amplified and (iii) the amounts of amplified products are measured. The reference RNA sequence can be used as an internal standard. The reference RNA sequence comprises a sequence present in the target viral RNA sequence and a sequence that is not present in the target viral RNA sequence. The reference RNA sequence and the target RNA sequence can be amplified by different oligonucleotides. The amplified target viral RNA sequence and the amplified reference RNA sequence can be distinguished by size or by probes. These claims only relate to the amplification of a target viral RNA sequence and a reference sequence.

B. Quantitation of Target Viral RNA Sequence

In a second aspect, claims 249-255 are directed to a method for the quantitation of target viral RNA in a sample. In accordance with this aspect, (i) a known quantity of a reference RNA sequence is added to a sample containing a viral RNA sequence, (ii) the target viral RNA sequence and the known quantity of the reference RNA sequence are simultaneously amplified, (iii) the amounts of amplified products are measured and (iv) the relative amount of the target viral RNA present in the sample before amplification is determined from the amounts of the

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amplified target viral RNA sequence and the amplified reference RNA sequence. The reference RNA sequence can be used as an internal standard. The reference RNA sequence comprises a sequence present in the target viral RNA sequence and a sequence that is not present in the target viral RNA sequence. The reference RNA sequence and the target RNA sequence can be amplified by different oligonucleotides. The amplified target viral RNA sequence and the amplified reference RNA sequence can be distinguished by size or by probes. These claims only relate to the quantitation of the amount of viral RNA present in the sample.

Board's New Grounds of Rejection Based on Interference Estoppel

In the Decision on Request for Rehearing, the Board treated as a new grounds of rejection both new grounds of rejection raised in the Decision on Appeal. The first new grounds of rejection raised in the Decision on Appeal was that claims 190, 199, 208, 217 and 249-255 were rejected because Applicants were estopped from claiming subject matter that is not patentably distinct from the count in Interference No. 105,055 citing *In re Deckler*, 977 F.2d 1449 (Fed. Cir. 1992) and *In re Kroekel*, 803 F.2d 705 (Fed. Cir. 1986). The Board concluded that the claims on appeal included the use of primers that are the same or different whereas the interference count required the use of the same primers. As a result the Board concluded that the claims did not exclude subject matter of the count, i.e., the use of the same primers.

In response to this new grounds of rejection by the Board, Applicants have amended claims 190, 199, 208, 217 and 249-255 to delete the language "the same or" and have thus limited the claims to the use of different primers. For this reason, Applicants submit that the claims do not include the subject matter of the interference count, are not barred by interference estoppel and are therefore patentable to Applicants.

In view of the above amendments and remarks, Applicants submit that claims 190-225, 242-245 and 249-251 are not barred by interference estoppel based on *In re Deckler* and *In re Kroekel*. Withdrawal of this new grounds of rejection is requested

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Board's New Grounds of Rejection Based on Estoppel Under 37 C.F.R. § 1.658(c)

In the Decision on Request for Rehearing, the Board treated as a new grounds of rejection both new grounds of rejection raised in the Decision on Appeal. The second new grounds of rejection raised in the Decision on Appeal (for which the reasoning was modified in the Decision on Request for Rehearing) was that claims 190, 199, 208, 217 and 249-255 were rejected based on estoppel under 37 C.F.R. § 1.658(c). In the Decision on Rehearing, the Board concluded that Applicants could have moved under 37 C.F.R. § 1.633 to add rejected claims 190, 199, 208, 217 and 249-255 which included the use of primers which are different or the same and thus would have been generic to the use of the same primers required by the interference count.

In response to this new grounds of rejection by the Board, Applicants have amended claims 190, 199, 208, 217 and 249-255 to delete the language "the same or" and have thus limited the claims to the use of different primers. Applicants submit that the use of different primers as now required by the amended claims is not generic to the use of the same primers. Since the language of the amended claims is not generic, the amended claims could not have been added to the interference under 37 C.F.R. § 1.633 because the Wang patents involved in the interference did not support the use of different primers. In addition, the amended claims would not define interfering subject matter between the instant application and the Wang patents because different primers and the same primers are not the same invention and neither is a genus or a species to the other. For all of these reasons, Applicants submit that the claims do not include the subject matter of the interference count, could not have been added to the interference, are not barred by estoppel under 37 C.F.R. § 1.658(c) and are therefore patentable to Applicants.

In view of the above amendments and remarks, Applicants submit that claims 190-225, 242-245 and 249-251 are not barred by estoppel under 37 C.F.R. § 1.658(c). Withdrawal of this new grounds of rejection is requested

Concluding Comments

In view of the above amendments and remarks, it is submitted that the amended claims are not barred by (a) interference estoppel based on *In re Deckler* and *In re Kroekel* or

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(b) estoppel under 37 C.F.R. § 1.658(c). Reconsideration of this application and early notice of allowance is requested. The Examiner is invited to telephone the undersigned if it will assist in expediting the prosecution and allowance of the instant application.

Respectfully submitted,

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